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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/720,513	03/26/2001	Therese Jourdier	MBHB00-1282	3546

20306 7590 02/13/2003

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EXAMINER
LI, BAO Q

ART UNIT	PAPER NUMBER
1648	12

DATE MAILED: 02/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/720,513	JOURDIER ET AL.	
	Examiner	Art Unit	
	Bao Qun Li	1648	

-- Th MAILING DATE of this communication appears on th cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/26/2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 10-15 are pending.

Reopen

This is reopen prosecution because after reconsidering the claimed invention, new grounds of rejections are requested for the record of the prosecution. Office apologize any inconveniency that brought by this reopen practice.

Sequence requirements

This application contains sequence disclosure in lines 11 of page 12 that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Full compliance with the sequence rules is required in response to this Office Action. A complete response to this office action should include both compliance with the sequence rules and a response to the Office Action set forth below. Failure to fully comply with **both** these requirements in the time period set forth in this office action will be held non-responsive.

Response to Amendment

This is a response to the argument submitted in appeal Brief, paper No. 11, filed 12/26/02. Claims 10-15 are considered before the examiner.

Please note any ground of rejection(s) that has not been repeated is removed. Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

New Grounds of Rejections:

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 10-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Sarkisov et al. (US Patent No. 4,368,191).

3. Sarkiso et al. teach a method for immunize an animal comprising an intramuscular injecting an effective amount of a vaccine composition comprising an antigen of pathogen Trichophyton mentagrophytes into the animal thigh. Therefore, the claimed invention is anticipated by the cited reference.

Claim Rejections - 35 USC §103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 10-15 are rejected under 35 U.S.C. 102(a) as being unpantenable over Carrano et al. (WO 95/26718A1), Groswasser et al. (Pediatrics 1997, Vol. 100, page 400-403), Stites et al. (Medical Immunology edited by Stites et al. 1997, pages 782, Appleton & Lange, Stamford, Connecticut) and Bouvet et al. (Infect. Immun. 1994, Vol. 62, pp. 3957-3961).

6. The claimed invention is directed to a method for inducing a systematic and local immune response of IgA, IgG or IgM antibodies or B cells secreting said antibodies by administering the antigen composition into thigh of human, preferably the quadriceps, wherein the immunogens are derived from the pathogen that have the gateway to entry into the host through the rectal, genital and/or urinary mucous membranes, such as HIV, herpes virus, candida species, chlamydia species, genital mycoplasmas, human pappilloma virus (HPV) etc.

7. Carrano et al. disclose method of immunization of human being comprises introduction of a genetic construct into an individual by intramuscularly or skin injection, wherein the

construct encodes an antigen from various pathogen selected form group consisting of HIV, human pappiloma virus (HPV), herpes simplex 1 virus type I and 2, etc. (claims 18-19). Carrano et al. do not explicitly teach which muscle is used for the injection, and measurement of local and systemic immune responses.

8. However, it is well known that the common sites for the intramuscular injection of vaccine are either at the arm or thigh. A better immune response has been reported with intramuscularly injection at the tight of leg, particularly with the quadriceps as evidenced by Groswasser et al. (Pediatrics 1997, Vol. 100, page 400-403) and Stites et al. (Medical Immunology edited by Stites et al. 1997, pages 782, Appleton & Lange, Stamford, Connecticut). Stities et al. teach that recent studies of injection techniques suggest that the arterolateral thigh or deltoid site is preferable to the buttocks. In adults, most injections meant for intramuscularly delivery are instead of delivery into fat. Groswasser et al. disclose that a better immune response for intramuscular compared with subcutaneous injection has been seen with several vaccines, such as the hepatitis B, rabies and influenza vaccines (See first paragraph on page 400), wherein the thigh injection referred by Dr. Groswasser et al. is the site of quadriceps (See section of materials and methods on page 401). Both Groswasser et al. and Stites et al. do not particular address correlation of local immune response with parental vaccination strategy.

9. Bouvet et al. teach that the systematic vaccination can be efficient at the genital level and thus could reinforce or even replace a local vaccine. Bouvet et al. immunized intramuscularly five women, 30-40 years old with purified tetanus toxoid (> 40IU) with aluminum hydroxide (< 1.25 mg) as adjuvant, and tested the serum and secreted IgG and IgA antibodies titers of blood, vagina or saliva. They found that the systematic vaccination of tetanus toxoid leads to a substantial rise of local IgG antitoxins, which are most likely have a systemic origin and can occur in the absence off specific Sig. They concluded that systemic-derived immunity in human genital secretions reinforces the potential interest in vaccines given by the parenteral rout in prevention of sexually transmitted diseases because they have showed that an intramuscularly immunization can locally induce for a long period of time a high levels of antibodies, which might be protective against the corresponding pathogen, given the efficacy of the injection antigen. They further teach that the possible of inducing protective antibodies by current procedures before development of true secretory vaccine seems to be of major interest because

the antibodies in secretions can play a key role against the pathogens, which remain in the genital area, by increasing their clearance with mucus and by inhibiting their attachment to the mucus. These antibodies could thus decrease, or even suppress, the entry of pathogens through the mucus and avoid overloading of the systemic defenses. Such mechanisms could be useful against sexual transmission of HIV by preventing the virus from reaching the systemic immune system (Se section of Discussion on pages 3959-3960).

10. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention was filled to be motivated by the teaching of Bouvet et al. to use the parenteral immunization strategy taught by Groswasser et al. and Stites et al. for immunizing human with the vaccine compositions as disclosed by Carrano et al. to protect the sexual transmitted diseases, such as HIV, HPV, HSV and others because the intramuscular systemic immunization can induce a same increase of local antibodies secreted from the mucosal and congenital routs, which may provide a local immune defense against the entry of the sexual transmitted pathogens. As there are no unexpected results have been provided, such as the thigh quadriceps injection of an antigen is able to get a significant higher local antibody response compared with the antibody induced by injecting same amount of said antigen in other muscles of the body, the claimed invention as a whole is prima facie obvious absence unexpected results.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 703-305-1695. The examiner can normally be reached on 8:00 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Bao Qun Li

James C. Housel

JAMES HOUSEL 2/10/03
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

February 06, 2003